



<p>Substitute for form PTO-891 FATIGUE AND STRESS</p> <h1>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h1> <p>(use as many sheets as necessary)</p>		Complete If Known	
		Application Number	10/725,484
		Filing Date	December 3, 2003
		First Named Inventor	Ramon A. Torres
		Group Art Unit	1648
		Examiner Name	Bo Peng
Sheet	1	of	1
		Attorney Docket Number	
		TORRES1B	

Examiner Signature	/Bo Peng/	Date Considered	07/13/2006
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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 801.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	NOT YET ASSIGNED
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				First Named Inventor	Ramon TORRES
				Group Art Unit	
				Examiner Name	
Sheet 4		of 8	Attorney Docket Number TORRES=1B		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T ²
SP	CO	KOSMISKI et al., "An increase in abdominal girth on protease inhibitor therapy is associated with visceral obesity and metabolic disturbances that closely resemble syndrome", <u>1st International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV</u> , 49-55 (1999)			
	CP	HENRY et al., "Atorvastatin and gemfibrozil for protease-inhibitor-related lipid abnormalities", <u>The Lancet</u> , 352:1031-1035 (1998)			
	CQ	ENGELSON et al., "Altered body fat distribution in HIV infection:regional body composition measurements by whole body MRI and DXA scans", <u>12th World AIDS Conference Geneva</u> , 471-471 (June 28-July 3 1998)			
	CR	HENRY et al., "Severe premature coronary artery disease with protease inhibitors", <u>The Lancet</u> , 351:1328 (1998)			
	CS	CARR et al., "Pathogenesis of HIV-1-proteases inhibitor-associated peripheral lipodystrophy, hyperlipidaemia, and insulin resistance", <u>The Lancet</u> , 351:1881-1883 (1998)			
	CT	CARR et al., "A syndrome of peripheral lipodystrophy, hyperlipidaemia and insulin resistance in patients receiving HIV protease inhibitors", <u>AIDS</u> , F51-F58 (1998)			
	CV	BRINKMAN et al., "The first international workshop on adverse drug reactions and lipodystrophy in HIV session 4: related syndromes mitochondrial toxicity of nucleosides" <u>The Body; An AIDS and HIV Information Resource</u> , Abstract No. 9 (1999)			
	CW	ABSTRACT - TORRES et al., "The effect of recombinant human growth hormone on protease-inhibitor-associated fat maldistribution syndrome", 675 <i>1999</i>			
	CX	ABSTRACT - VIARD et al., "Lipodystrophic syndromes in a cohort of HIV-1-infected patients receiving HAART with a protease inhibitor", Abstract No. 026 <i>1999</i>			
	CY	WANKE et al., "Recombinant human growth hormone improves the fat redistribution syndrome (lipodystrophy) in patients with HIV", <u>AIDS</u> , 2099-2103 (1999)			
	CZ	ABSTRACT 031 - RUIZ et al., "A multicentre, randomized, open-label, comparative trial of the clinical, immunological and virological benefit of switching the PI by nevirapine in HAART-experienced patients suffering lipodystrophy", 35 <i>1999</i>			
	DA	ABSTRACT 068 - ROZENBAUM et al., "Prospective follow-up of a PI substitution for efavirenz in patients with HIV-related lipodystrophy syndrome" <i>1999</i>			
SP	DB	ABSTRACT 054 - MOLYLE et al., "Changes in visceral adipose tissue and blood lipids in persons reporting fat redistribution syndrome switched from PI therapy to efavirenz" <i>1999</i>			

Examiner Signature	<i>Ramon Torres</i>	Date Considered	11/14/05
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

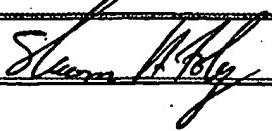
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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
SP	DC	MILLER et al., "Visceral abdominal-fat accumulation associated with use of Indinavir", <u>The Lancet</u> , 351:871-875 (1998)	
	DD	ABSTRACT 042 - MILANO et al., "Two case reports of unusual lipomatous growths associated with combination antiretroviral therapy" 1999	
	DE	ABSTRACT 038 - MAGGI et al., "Precocious lesions of the carotid vessels in HIV-1-infected patients treated with protease inhibitors" 1999	
	DF	ABSTRACT 018 - MERCIE et al., "Case report of lipodystrophy observations in patients naive of protease inhibitor treatment, anquilaine cohort" 1999	
	DG	KRENTZ et al., "Anthropometric, metabolic, and immunological effects of recombinant human growth hormone in AIDS and AIDS-related complex", <u>Journal of Acquired Immune Deficiency Syndromes</u> , 6(3):245-251 (1993)	
	DH	ENGELSON et al., "Fat distribution in HIV-infected patients reporting truncal enlargement quantified by whole-body magnetic resonance imaging", <u>Am J Clin Nutr</u> , 69:1162-1169 (1999)	
	DI	BECKER et al., "A nondiabetogenic derivative of human growth hormone", 342:108 1999	
	DJ	BJORNTORP et al., "Review the regulation of adipose tissue distribution in humans", <u>International Journal of Obesity</u> , 20:291-302 (1996)	
	DK	CARR et al., "Diagnosis, prediction, and natural course of HIV-1 protease-inhibitor-associated lipodystrophy, hyperlipidaemia, and diabetes mellitus: a cohort study", <u>The Lancet</u> , 353:2093-2099 (1999)	
	DL	CHEN et al., "The human growth hormone locus: nucleotide sequence, biology, and evolution", <u>Genomics</u> , 4:479-497 (1989)	
	DM	ABSTRACT 006 - ENGELSON et al., "Effect of recombinant human growth hormone in the treatment of visceral fat accumulation in HIV infection: interim analysis", <u>Antiviral Therapy</u> , 4(Supplement 2):19 (1999)	
	DN	HSIUNG et al., "Use of bacteriocin release protein in E. Coli for excretion of human growth hormone into the culture medium", <u>Bio/technology</u> 7:267-271 (1989)	
SP	DO	JONES et al., "Crystallization of authentic recombinant human growth hormone", <u>Bio/technology</u> , 5:499-500 (1987)	

Examiner Signature		Date Considered	11/14/15
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				Group Art Unit	
				Examiner Name	
Sheet	5	of	8	Attorney Docket Number	TORRES=1B

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T ²
SP	DP	LEWIS et al., "A naturally occurring structural variant of human growth hormone", <u>The Journal of Biological Chemistry</u> , 253:2679-2687 (1978)			
	DQ	LEWIS et al., "Altered proteolytic cleavage of human growth hormone as a result of deamidation", <u>The Journal of Biological Chemistry</u> , 11645-11650 (1981)			
	DR	ZUREK et al., "Human growth hormone: complementary DNA cloning and expression in bacteria", <u>Science</u> 205:602-607 (1979)			
	DS	ABSTRACT P145 - MAUSS et al., "Successful treatment of PI-induced visceral abdominal-fat accumulation with R-human growth hormon" 1998			
	DT	MOCROFT et al., "Changes in AIDS-defining illnesses in a London clinic, 1987-1998", <u>Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology</u> , 21:401412 (1999)			
	DU	MOORE et al., "Equivalent potency and pharmacokinetics of recombinant human growth hormones with or without an N-terminal methionine", <u>Endocrinology</u> , 122:2920-2926 (1988)			
	DV	WINDISCH et al., "Recombinant human growth hormone for AIDS-associated wasting", <u>The Annals of Pharmacotherapy</u> , 32:437-445 (1998)			
	DW	KOTLER et al., "Studies of body composition and fat distribution in HIV-infected and control subjects", <u>Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology</u> , 20:226-237 (1999)			
	DX	PINEDA, "Predictable upwelling and the shoreward transport of planktonic larvae by internal Tidal Bores", <u>Science</u> , 548 1991			
	DY	CARR et al., "Pathogenesis of HIV-1-protease inhibitor-associated peripheral lipodystrophy, hyperlipidaemia, and insulin resistance" <u>The Lancet</u> , 351:1881-1883 (1998)			
	DZ	CARR et al., "Fast track a syndrome of peripheral lipodystrophy, hyperlipidaemia and insulin resistance in patients receiving HIV protease inhibitors", <u>AIDS</u> , 12:F51-F58 (1998)			
	EA	MICHAELS et al., "Differences in the incidence rates of opportunistic processes before and after the availability of protease inhibitors", <u>5th Conference on Retroviruses and Opportunistic Infections</u> , (February 1-5, 1998)			
SP	EB	DONG et al., "Diabetes and use of protease inhibitors", <u>12th World AIDS Conference Geneva</u> , (June 28 - July 3 1998)			

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